REMARKS

Applicants have discovered a method for the production of cell-specific retroviral vectors.

Claims 1-9 and 19-20 are pending in the application, claims 10-18 having been canceled, and news claim 19 and 20 having been added by the above amendment. Claims 1-9 have been amended to correct typographical errors and to correct the language structure of the claims. Claim 9 has been amended to recite SEQ ID NO:1. New claim 19 also recites SEQ ID NO:1. Support for amended claim 9 and new claim 19 can be found in the specification, at, for example, the paragraph beginning on page 5, line 12 (as filed and as amended by way of a Supplemental Preliminary Amendment, filed on January 17, 2002). New claim 20 is supported by, for example, original claim 1. No new matter has been added.

Applicants acknowledge receipt of the initialed and dated copy of the IDS Form 1449, Paper No. 5.

Specification

The specification has been amended to recite the priority claim on the first line of page 1.

Drawings

The drawings have been amended as specified in the Notice of Draftsperson's Review. Figures 1-3 have been amended to remove unnecessary shading and to ensure that they are plain and legible. Figures 4A and 4B have been enlarged so that the height of the numbers, letters and characters are at least 0.32 cm (1/8 in.). The figures, as amended, are believed to satisfy the requirements of 37 C.F.R. 1.84(i) and (p).

35 U.S.C. §112, first paragraph

The Examiner rejected claims 1 and 9 for lack of enablement (Office action at page 3). This ground for rejection is respectfully traversed.

The Examiner states that a particular plasmid vector is required to practice the present invention. The Examiner states, "[i]t is apparent [that a] specific vector – pTC53 – is required to practice the claimed invention" (Office action at page 3). The Examiner then concludes that pTC53 "must be readily available or obtainable by a repeat method set forth in the specification, or otherwise known and readily available to the public" (Office action at page 3).

While the method now claimed can be performed with pTC53 (but is not so limited), one of ordinary skill in the art would be able to make and use that vector without resort to undue experimentation. Expression vectors, particularly plasmid vectors, are well known to those who work in the field of the invention, and they are made and used on a routine basis – probably daily in hundreds of laboratories. Moreover, the present specification provides all the information necessary to make pTC53. The Examiner's attention is directed to Figure 1 (the substitute sheet appended to the present amendment is much clearer than that filed with the application), where the components of pTC53 are shown, and to Figure 4, which provides the nucleotide sequence of pTC53 (SEQ ID NO:1). Given this information, one of ordinary skill in the art would certainly be able to generate pTC53. There is little need for experimentation at all, let alone undue experimentation. Thus, even if the Examiner maintains that a specific biological material is required to practice the method now claimed, there is no need for a deposit because that material can be readily obtained. *See* MPEP at 2404.02 citing *Ex Parte Jackson*, 217 USP 804 (Bd. App. 1982) and *Tabuchi v. Nubel*, 559 F.2d 1183, 194 USPQ 521 (CCPA 1977).

Claim 9, which was also rejected under 35 U.S.C. § 112, ¶ 1, has been amended to specify that the psi-negative retroviral Env expression vector of claim 1 includes the sequence of SEQ ID NO:1 (which represents the sequence of pTC53).

In view of the present amendment, and for the reasons stated above, the Examiner is respectfully requested to reconsider and withdraw this ground for rejection.

35 U.S.C. §102(e)

The Examiner rejected claims 1-8 as being anticipated by Dornburg (U.S. Patent No. 5,869,331; herein, "Dornburg") as evidenced by Novotny *et al.* ("Immunology," pp. 449-458, in Molecular Biology and Biotechnology, 1995; herein, "Novotny"). This ground for rejection is respectfully traversed.

In order for a claimed method to be unpatentable for lack of novelty, that method – the exact method claimed --must be found in the prior art. "'A claim is anticipated only if each and every element as set forth in the claim is found, whether expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)" (MPEP at 2131).

Dornburg discloses a retroviral particle that includes a nucleic acid encoding a single-chain antibody fragment (scFV) fused to the SNV *env* gene. However, Dornburg says nothing about making that particle with a sequence obtained by a process that begins with injecting a mammal with population of cells. Dornburg constructed a targeting envelope by using the known sequence of a previously identified single chain antibody (and the Examiner appears to recognize this by referring to the antibody molecule described in Dornburg at column 4, lines 25-34, and to the specific and previously known single chain antibody gene termed B6.2). Dornberg does not teach immunizing a mammal with one or more desired target cell populations (as required by step (a) of claim 1 of the instant application). This deficiency remains despite Novotny. Although the production of single chain antibody may have become a standard technique, that does not change the fact Dornburg did not suggest immunizing a mammal with a cell population (nor any of the subsequent steps required in the present claims to arrive at the sequence of the scFV of Applicants' vectors). Neither Dornburg nor Novotny teach all of the steps of the methods now claimed; there is no prior art disclosure of a method that is identical to that now claimed. Absent that, the rejection for lack of novelty should be withdrawn.

No fees are believed to be due. Any charges or credits can be applied to Deposit Account No. 06-1050, referencing Attorney Docket No. 11692-004001.

Respectfully submitted,

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